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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,881	08/16/2001	Arthur A. Bertolero	ESTC-004	5712
23429	7590	01/30/2004	EXAMINER	
GREGORY SMITH & ASSOCIATES 3900 NEWPARK MALL ROAD, 3RD FLOOR NEWARK, CA 94560			MAYNARD, JENNIFER J	
			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 01/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,881

Applicant(s)

BERTOLERO ET AL.

Examiner

Jennifer J Maynard

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1-14, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10, 12, 13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresnahan et al. (US 6,117,105 A) in view of Schneiderman (US 5,782,740 A).

Bresnahan et al. discloses a multichannel catheter (200), as depicted in Figure 9, useful for delivering extracorporeal blood to a mammal in need thereof by insertion into a blood vessel of the mammal, which catheter has a defined length with distal and proximal ends and comprises a central, first channel (210) defined by a surrounding wall extending substantially the length of the catheter, which channel is closed at its distal end, see Figure 11; a second channel (216) extending substantially the length of the catheter parallel to the first channel but independent thereof, being integrated into the wall of the first channel, and being open at its distal end (236); a plurality of openings (226) for the outflow of the blood in the wall of the catheter communicating only with said first channel; an inflatable bladder (220) integrated into the distal end of the catheter between the openings for the outflow of blood and the second channel distal opening; and a third channel (214) extending substantially the length of the said catheter integrated into the wall of the first channel, being parallel to the first and second channels but independent thereof, and having a distal opening (230) in fluid communication with the interior

Art Unit: 3763

of the bladder. The catheter may be configured for retrograde deployment via a peripheral artery, such as the femoral artery, or it may be configured for antegrade deployment via an aortotomy incision or direct puncture in the ascending aorta, see Column 2, lines 41-45, Column 6, lines 54-62, Column 10, lines 24-28, and Column 12, lines 39-42.

Bresnaham et al. fails to disclose a solid flexible shaft slidably engageable into the first channel extending substantially the length of the first channel.

Schneiderman discloses a multichannel catheter, as depicted in Figures 1, 1A, 2 and 3, which catheter has a defined length with distal and proximal ends and comprises a central, first channel (19) defined by a surrounding wall extending substantially the length of the catheter, which channel is closed at its distal end (20); a second channel (14) extending along the length of the catheter parallel to the first channel but independent thereof, being integrated into the wall of the first channel, and being open at its distal end (15); an inflatable bladder (34) integrated into the distal end of the catheter; a third channel (16) extending substantially the length of the said catheter integrated into the wall of the first channel, being parallel to the first and second channels but independent thereof, and having a distal opening in fluid communication with the interior of the bladder; and a solid flexible shaft (21) slidably engageable into the first channel extending substantially the length of the first channel.

It would have been obvious to one having ordinary skill in the art to have modified Bresnaham et al.'s multichannel catheter device with a solid flexible shaft, separate and distinct from a guidewire, as taught by Schneiderman, so as to improve the pushability and strength of the catheter as it tracks along the guidewire.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bresnahan et al. (US 6,117,105 A) in view of Schneiderman (US 5,782,740 A) as applied to claims 1-8, 10, 12, 13, 18 and 19 above, and further in view of Orth (US 5,542,925 A).

Bresnahan et al. in view of Schneiderman disclose the invention as claimed with the exception of at least one opening in the first channel is elongate with the length of the elongate opening being parallel to the length of the catheter.

Orth discloses a multichannel catheter (10), as depicted in Figure 1, which catheter has a defined length with distal and proximal ends and comprises a first channel (21) defined by a surrounding wall (16) extending substantially the length of the catheter; a second channel (20) extending substantially the length of the catheter parallel to the first channel but independent thereof and having a distal opening in fluid communication with the interior of the bladder; a plurality of openings or oblong perfusion ports (23, 24) are provided in one or more wall portions for communicating with the first channel, see Column 3, lines 1-22; and an inflatable bladder (13) integrated into the distal end of the catheter.

It would have been obvious to one having ordinary skill in the art to have substituted Bresnahan et al. in view of Schneiderman's multichannel catheter's plurality of openings with oblong openings as taught by Orth, so as to dimension the ports to have lengths which are at least 50 % greater than their widths to thereby render the widths of the perfusion ports dimensioned to be small enough to prevent the passage of the shaft/reinforcing mandrel/guidewire therethrough, while allowing for adequate blood flow through the openings/ports. Alternatively, it would have been obvious to have substituted Bresnahan et al. in view of Schneiderman's multichannel

Art Unit: 3763

catheter's plurality of circular openings with oval or oblong shaped openings because they were a well-known alternative to round holes, see d'Ambrosio (US 5,697,905 A) Column 5, lines 2-9.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bresnahan et al. (US 6,117,105 A) in view of Schneiderman (US 5,782,740 A) as applied to claims 1-8, 10, 12, 13, 18 and 19 above, and further in view of Coleman et al. (US 5,928,181 A) or Bolger et al. (US 5,437,290 A).

Bresnahan et al. in view of Schneiderman disclose the invention as claimed with the exception of markings positioned near the proximal end of the catheter to mark the distance from the distal end of the catheter.

Coleman et al. discloses a multichannel catheter (1), as depicted in Figures 1A and 1B, which catheter has a defined length with distal and proximal ends and comprises a central, first channel (2') defined by a surrounding wall extending substantially the length of the catheter; a second channel (8') extending along the length of the catheter parallel to the first channel but independent thereof, being integrated into the wall of the first channel, and being open at its distal end (15); an inflatable bladder (3) integrated into the distal end of the catheter; and a third channel (3') extending substantially the length of the said catheter integrated into the wall of the first channel, being parallel to the first and second channels but independent thereof, and having a distal opening in fluid communication with the interior of the bladder. In order to facilitate accurate positioning of the catheters, along the distal end portions of the arterial and venous catheters, radiopaque markers may be provided at or adjacent to these catheter structures in order to use X-ray or fluoroscopic visualization when guiding the catheters into place. In the

Art Unit: 3763

alternative or in addition to such radiopaque markers, markers or other indicia may also be provided on the proximal end portions of these catheters such that the catheters in vivo position is determinable when the catheter is observed to advance a predetermined distance beyond an introducer sheath or guiding catheter according to the positioning of such proximal indicia relative to the introducer or guiding catheter, see Column 34, line 57 through Column 35, line 14.

Bolger et al. discloses a system and method for monitoring the intraluminal position of a vascular catheter (12, 50), wherein axially spaced-apart markings (18, 56) are provided along at least a portion of the catheter length. The penetration depth of the catheter into the lumen is monitored by a detector (16), which detects passage of the markings.

It would have been obvious to one having ordinary skill in the art to have modified Bresnahan et al. in view of Schneiderman's multichannel catheter with markings positioned near the proximal end of the catheter to mark the distance from the distal end of the catheter, so as to ensure accurate positioning of the device within the vasculature without requiring fluoroscopic imaging equipment.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bresnahan et al. (US 6,117,105 A) in view of Schneiderman (US 5,782,740 A) as applied to claims 1-8, 10, 12, 13, 18 and 19 above, and further in view of Valley et al. (US 5,766,151 A).

Bresnahan et al. in view of Schneiderman disclose the invention as claimed with the exception of the inflatable bladder, when inflated and viewed longitudinally, is of a cylindrical shape.

Art Unit: 3763

Valley et al. discloses a multichannel catheter (10, 790, 820), as depicted in Figures 2, 21 and 23A, which catheter has a defined length with distal and proximal ends and comprises a central, first channel (40) defined by a surrounding wall extending substantially the length of the catheter; a second channel (43) extending along the length of the catheter parallel to the first channel but independent thereof, being integrated into the wall of the first channel, and having a distal opening in fluid communication with the interior of the bladder; and an inflatable bladder (11, 792, 812) integrated into the distal end of the catheter, wherein the bladder may be of a cylindrical, spherical, ellipsoidal or other appropriate shape to fully and evenly accommodate the lumen of the ascending aorta, see Column 5, lines 37-41.

It would have been obvious to one having ordinary skill in the art to have modified This maximizes the Bresnahan et al. in view of Schneiderman's multichannel catheter's inflatable bladder with a cylindrical shape, as taught by Valley et al., so as to provide adequate surface area contact with the aorta allowing for even distribution of occlusive pressure.

Double Patenting

Claims 1 and 3-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,868,703 A in view of Schneiderman (US 5,782,740 A).

The application's claims are broader in some respects, see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), and merely add a solid flexible shaft slidably engageable into the first channel extending substantially the length of the first channel in other respects, this feature was absent from the patent claim.

Schneiderman discloses a multichannel catheter, as depicted in Figures 1, 1A, 2 and 3, which catheter has a defined length with distal and proximal ends and comprises a central, first channel (19) defined by a surrounding wall extending substantially the length of the catheter, which channel is closed at its distal end (20); a second channel (14) extending along the length of the catheter parallel to the first channel but independent thereof, being integrated into the wall of the first channel, and being open at its distal end (15); an inflatable bladder (34) integrated into the distal end of the catheter; a third channel (16) extending substantially the length of the said catheter integrated into the wall of the first channel, being parallel to the first and second channels but independent thereof, and having a distal opening in fluid communication with the interior of the bladder; and a solid flexible shaft (21) slidably engageable into the first channel extending substantially the length of the first channel.

It would have been obvious to one having ordinary skill in the art to have claimed a solid flexible shaft, separate and distinct from a guidewire, as taught by Schneiderman, so as to improve the pushability and strength of the catheter as it tracks along the guidewire.

Allowable Subject Matter

Claims 15-17 are allowed.

Conclusion

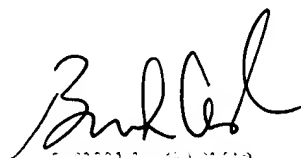
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard



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